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JUL 2 1 2003

510(k) SUMMARY

K 031638

1 DATE PREPARED

May 21st, 2003

2 CONTACT PERSON

Warren Baker
President, Chief Executive Officer
(Official Correspondent)

3 DEVICE NAME

Proprietary Name:	**CARDIO VASCULAR INFORMATION ENHANCED WORKSTATION™ (CVIEW)™**
Common Name:	DICOM Workstation
Radiology Panel:	90LLZ - System, Image Processing
Classification Name	Picture Archiving and Communications Systems (PACS) 21CFR892.2050 (Federal Register / Vol. 63, No. 82 / April 29, 1998)

4 DEVICE DESCRIPTION AND INTENDED USE

Cardio Vascular Information Enhanced Workstation™ (CVIEW)™ is a viewing stations for Cath, Echo and Angio case studies, represent the next generation in network cardiac review systems. Features include 1024 viewing, security, report generation, multi-modality viewing, databasing as well as instant access to hundreds of cases on-line or thousands through the network.

440, Armand-Frappier blvd., Suite 250, Laval (Quebec) H7V 4B4 Canada Tél.: (450) 681-6810 Fax.: (450) 681-3925 1-877-711-6810 www.electromed.com

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5 SUBSTANTIAL EQUIVALENCE TO PREDICATE DEVICE(S)

Substantially Equivalent (Predicate) Devices

Product Tradename	Manufacturer	510(k) Number
ViewNT	Electromed International	K000474
Centricity PACS Plus	GE Medical Systems	K023557
Video Plus System & Echocardiography System	Camtronics Medical Systems	K992666 & K992259
Impax Workstation	AGFA Corporation	K022292

6 SAFETY AND EFFECTIVENESS

The intended use and technological characteristic of the **Cardio Vascular Information Enhanced Workstation (CVIEW)™** are similar or equivalent to the Predicate Device(s). Any differences between the **CVIEW™**and the Predicate Device(s) have no significant influence on the safety and/or effectiveness of the Device.

7 CLINICAL PERFORMANCE DATA

Not required for determination of substantial equivalence for this type and class of device.

8 CONCLUSION DRAWN FROM CLINICAL AND NONCLINICAL TEST DATA

Not required for determination of substantial equivalence for this type and class of device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 1 2003

Mr. Warren Baker
President, Chief Executive Officer
Electromed Imaging
440 boul. Armand-Frappier,
bureau 250, Laval (Québec)
H7V 4B4
CANADA

Re: K031638
Trade/Device Name: Cardio Vascular Information Enhanced Workstation™ (CVIEW™)
Regulation Number: 21 CFR 892.1000
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: May 22, 2003
Received: June 4, 2003

Dear Mr. Baker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Indication for Use Statement

510(k) Number:(if known): K031638

Device Name: **Cardio Vascular Information Enhanced Workstation™ (CVIEW™)**

Indications for Use:

The CVIEW™ is a high performance, digital, cardiac image viewer. The System supports DICOM 3.x and higher cardiac and angio images and displays them in their original dynamic mode. The CVIEW accepts images from DICOM 3.x CDs or can be configured to read DICOM 3 images from a DICOM Archive Server. The CVIEW allows immediate playback of images from any patient stored on the system and burning CDs in the DICOM part 10 - file format.

It represents the next generation in network cardiac review systems. Features include 1024 viewing, security, report generation, multi-modality viewing, databasing as well as instant access to hundreds of cases on-line or thousands through the network.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031638

Prescription Use ✓ OR Over-the-Counter Use

(per 21CFR801.109)

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